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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/894,018   | 06/27/2001  | Alessandro Sette     | 2060.0320003        | 7107             |
| 50710  | 7590        | 08/15/2006           | EXAMINER            |                  |
| STERNE, KESSLER, GOLDSTEIN & FOX, P.L.L.C.<br>1100 NEW YORK AVE.<br>WASHINGTON, DC 20005 |             |                      | ALLEN, MARIANNE P   |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1647                |                  |
| DATE MAILED: 08/15/2006  |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/894,018             | SETTE ET AL.        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Marianne P. Allen      | 1647                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-32, 34, 36, 59, 62-74, 77, 78 and 81-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-32, 34, 36, 59, 62-74, 77-78, and 81-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicant's arguments filed 6/2/06 have been fully considered but they are not persuasive.

Claims 81-83 have been newly added. Claims 27-32, 34, 36, 59, 62-74, 77-78, and 81-83 are under consideration by the examiner.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 27, 32, 34, 36, 59, and 72 under 35 U.S.C. 102(b) as being anticipated by Bergmann et al. (Reference NPL151) is obviated by applicant's amendment to the claims.

The rejection of claims 27, 59, and 72 under 35 U.S.C. 102(b) as being anticipated by Whitton et al. (Reference NPL165) is obviated by applicant's amendment to the claims.

### ***Claim Rejections - 35 USC § 112***

Claims 27-32, 34, 36, 59, 62-74, 77-78, and 81-83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims have been substantively amended and basis has been stated to be on page 34, lines 1-7, and page 36, line 17, through page 37, line 13. However, this is not agreed with.

Original claims 27 and 28 had a limitation requiring that the flanking or spacer amino acid residue prevents the occurrence of a CTL or HTL junctional epitope. This concept has been removed from the claims by the current amendment. Basis is not seen for the broader concept. Claims 72 and 73 are not originally filed claims and also do not include the limitation that the flanking or spacer amino acid residues prevent the occurrence of a CTL or HTL junctional epitope. Note that when spacers are discussed throughout the specification it is always in the context that they prevent the occurrence of CTL or HTL junctional epitopes.

Claims 27 and 72 have been amended to recite "selecting five or more epitopes." Basis is not seen for this concept. Page 28, line 13, discloses at least 10 CTL or HTL epitopes but five is not seen.

As set forth in the last Office action, basis for claims 59, 74, 77-78 is not seen. Pages 36-37 discuss analysis of a particular construct and not a general concept. The general steps set forth in these claims do not appear to be disclosed.

### ***Claim Rejections - 35 USC § 102***

Claims 28-29, 63, 73, and 78 are rejected under 35 U.S.C. 102(e) as being anticipated by Sette et al. (U.S. Patent No. 6,689,363 B1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Sette et al. discloses linking multiple CTL and HTL epitopes by small spacer molecules such as Ala or Gly. The corresponding minigenes are also disclosed. The patent discloses designing multi-epitope constructs in order to avoid junctional epitopes. Four class I and four class II epitopes are disclosed as being incorporated into a minigene for expression. See at least abstract; column 32; Examples 9-10 at columns 43-45; Example 14 at column 47; and claims.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

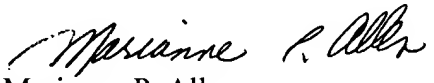
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Marianne P. Allen  
Primary Examiner  
Art Unit 1647  
8/10/06

mpa